METHODS AND COMPOSITIONS FOR PREVENTING AND TREATING AUDITORY DYSFUNCTIONS

[0001] This Application is a Continuation of U.S. application Ser. No. 16/506,904, filed on Jul. 09, 2019, which is a Continuation of U.S. application Ser. No. 15/854,660, filed on Dec. 26, 2017, now abandoned, which is a Division of U.S. application Ser. No. 15/230,257, filed Aug. 5, 2016, now issued as U.S. Pat. No. 9,889,107, which is a Division of U.S. application Ser. No. 13/907,590, filed May 31, 2013, now issued as U.S. Pat. No. 9,457,009, which claims the benefit of U.S. Provisional Application No. 61/653,577, filed May 31, 2012, and U.S. Provisional Application No. 61/701,397, filed Sep. 14, 2012, the contents of all of which are herein incorporated by reference in their entireties.

[0002] Throughout this application various publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

FIELD OF THE INVENTION

[0003] This invention relates to auditory dysfunctions (e.g., hearing loss, tinnitus, hyperacusis, and related auditory processing disorders) and methods of preventing and treating such dysfunctions. Additionally, this invention relates to specific chemicals and chemical compositions and the uses of such chemicals and chemical compositions for preventing and/or treating auditory dysfunctions.

BACKGROUND OF THE INVENTION

[0004] Auditory dysfunction in people is an ongoing problem in the medical fields of otology and audiology. Auditory dysfunctions typically arise from both acute and chronic exposures to loud sounds, ototoxic chemicals and aging. Sounds exceeding 85 decibels can cause hearing loss and is generated by sound sources such as, gun shots, exploding bombs, jet engines, power tools, and musical concerts. Other common everyday activities and products also give rise to high intensity noise such as use of hair dryers, MP3 players, lawn mowers, and blenders. Military personnel are particularly at risk for noise induced hearing loss due to typical military noise exposures. Side effects to noise induced hearing loss include tinnitus (ringing in the ears), diminished speech understanding, hyperacusis, recruitment and various types of auditory processing impairments. Exposures to commonly used medications may also induce auditory dysfunctions. For instance, patients treated with anticancer therapies, antibiotics and other medications often develop hearing loss as a side effect. Furthermore, exposure to industrial chemicals and gasses may induce auditory impairments. Lastly, auditory dysfunction is a common consequence of aging in Western societies.

[0005] Approximately 17 percent of Americans (estimated at 36 million) have hearing loss and half of that number are under the age of 65. It is predicted that the number of Americans with hearing loss will exceed 70 million by the year 2030.

[0006] About 300 million people worldwide currently suffer from moderate to severe hearing loss, and this number is expected to increase to 700 million by the year 2015. Most of these people will suffer from noise induced hearing loss and one in four Americans will develop permanent hearing loss as a result of occupational exposure to noise hazards. According to the Center for Commercialization of Advanced Technology, the Department of Defense and the VA, the VA spends over $1 billion on hearing loss compensation. The Navy, Marine Corps, and Air Force (combined) file 22,000 new hearing loss claims, and hearing loss costs the economy more than $56 billion per year.

[0007] Very few cases of hearing loss can actually be cured. Audiological devices such as hearing aids have limitations including the inability to improve speech intelligibility. Of those impacted by hearing impairments, less than 20 percent presently use hearing instruments.

[0008] In cases of age-related, noise- or drug-induced auditory dysfunctions, the only effective way to currently "treat" the disorder or reduce its severity is prevention: avoiding excessive noise and using ear protectors, practicing a healthy lifestyle, and avoiding exposure to ototoxic drugs and substances if possible.

[0009] Once the hearing loss has developed, people may use a hearing aid to correct the inability to hear. However, despite advances in the performance of these prostheses, they still have their limits. For example, hearing aids mainly amplify sound and cannot correct for suprathreshold or retrocochlear impairments such as impaired speech intelligibility, speech in noise deficits, tinnitus, hyperacusis, loudness recruitment and various other types of central auditory processing disorders. Hearing aids essentially amplify sounds which stimulate unimpaired cells but there is no therapy for aiding recovery of impaired cells or maximizing the function of existing unimpaired cells. In cases of complete or profound deafness, a cochlear implant may be used. This device transmits electrical stimuli via electrodes surgically implanted into the cochlea. A cochlear implant can be of particular help for deaf children if it is implanted around the age of two or three, the time when language skills are developing fastest. However, cochlear implants involve invasive surgery and are expensive. Furthermore, cochlear implants require viable neurons in order to achieve benefit.

[0010] Thus, there remains a long felt need to protect auditory cells before injury and preserve/promote the function of existing cells after injury. As disclosed below, the present invention provides a novel means for preventing and treating auditory dysfunctions.

SUMMARY OF THE INVENTION

[0011] The invention provides methods for treating auditory impairments in a subject in need of treatment comprising administering to said subject an effective amount of a composition comprising, as an active agent, one or more of a carboxy alkyl ester, a quinic acid derivative, a caffeic acid derivative, a ferulic acid derivative, or a quinic acid lactone or derivative thereof or pharmaceutically acceptable salt thereof and an acceptable carrier or excipient, so as to treat auditory impairments in the subject.

[0012] In one embodiment, the invention provides methods for treating auditory impairments in a subject comprising administering to said subject an effective amount of a composition comprising as an active agent one or more of a carboxy alkyl ester, alkaloid, pentacyclic alkaloid, tannin, or phytochemical derived from the inner bark or root of Uncaria tomentosa or derivative thereof or pharmaceutically acceptable salt thereof and an acceptable carrier or excipient, so as to treat auditory impairments in the subject.